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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,525	02/27/2004	Richard James Cawthray	02911.012130.	7746

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,525	CAWTHRAY ET AL.	
	Examiner	Art Unit	
	LEZAH ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 29, 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,4,11,14,25 and 26* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,4,11,14,25 and 26* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 June 2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed June 29, 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 1, 2, 4, 11, 14, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Kelly (US 4,817,819) in further view of Palo Alto Medical Foundation (January 2002).

Applicant's Arguments

Applicant argues that the calcium containing nutrient in the kit of the present invention is more than a memory aid, but serves a medicinal purpose to, in part, increase results of treatment with a bisphosphonate. The advantages and

nonobviousness of the present invention is supported by the Declaration. The claimed invention addresses the market need and leads to significantly superior results in the treatment of osteoporosis in patients taking bisphosphonates. Applicant further argues the Daifotis fails to suggest by way of example, any regimens administering doses of a calcium-containing nutrient and fails to teach the amount of the calcium containing nutrient. It also fails to identify vitamin D. Further Applicant argues that the reference discloses taking calcium on the same day as the bisphosphonate. It would not be obvious based on Daifotis to choose calcium and therefore the medical benefits taught and achieved by the present invention would not be attained. Kelly fails to remedy the deficiencies of Daifotis. Kelly does not teach administration of unit doses of an accompanying calcium-containing nutrient. They merely teach that seven tablets in the blister pack might be a placebo or non-active tablet. As in Daifotis, the purpose of the blister packs is generally to act as memory aids. Further, there is clearly no disclosure or suggestion of the amount of calcium, or vitamin D to be administered in the unit doses as presently claimed, e.g., about 400 mg to about 1500 mg of elemental calcium per day and about 100 IU to 10,000 IU per day of vitamin D. Palo Alto Medical Foundation fails to remedy the deficiencies of Daifotis and Kelly. Palo Alto Medical Foundation fails to specify a kit containing an active ingredient, and fails to offer any guidance on the dosing of the active in relation to the supplement and the benefits that may be achieved by a kit whereby simultaneous dosing is avoided. Like Daifotis, Kelly, and Palo Alto fail to teach or suggest the importance of correct dosing of a bisphosphonate and a calcium-containing nutrient, as fully explained in the Declaration,

to avoid simultaneous daily dosing and gain the health and medical advantages achieved by using the kit of the present invention.

Examiner's Response

The Examiner submits that Daifotis discloses that calcium or dietary supplements can be included into the kits. One of ordinary skill in the art would reasonably recognize that the calcium is used as a supplement as well as a placebo because it is known in the art that calcium is an element critical to many body functions, including bone growth and maintenance (Palo Alto Medical Foundation, page 1) and thus serves a medicinal purpose. The "advantages" and "nonobviousness" asserted by Applicant appear to be expected. Daifotis suggests methods of improving patient compliance by suggesting the compositions be stored in blister packs with memory aids. Kelly discloses such blister packs, although not for the same purpose. One of ordinary skill in the art would recognize the advantages of using the blister packs with the compositions of Daifotis because the blister packs are aids in helping the patients take their medication at the appropriate time.

The disclosure of Daifotis provides the means for avoiding simultaneous dosing of the bisphosphonate and the nutrient by disclosing the nutrient is taken on the days the bisphosphonate is not. Although it does not disclose the benefits of such dosing, it does clearly suggest the regimen. Further patient compliance and ease of administration would be achieved based on the teachings of Daifotis because Daifotis suggest packaging that would allow a patient to keep track of when to take the

disclosed bisphosphonates. This would facilitate correct dosing as disclosed by the Declaration.

Although Kelly does not teach calcium, it is used for its teaching of blister packs that use memory aids that assist in patient compliance. The blister packs comprise rows and columns and have the days of the week as a memory aid (Figures). Some blister packs have 4 rows which would include the 28 day period of the instant claims (Figures 9 and 10). Therefore the blister packs will improve patient compliance and the alleged unexpected results asserted by Applicant do not appear to be unexpected. The amount of calcium and vitamin D are disclosed by Palo Alto Medical foundation (PAMF). PAMF discloses recommended daily doses. Therefore when the calcium is used as a nutrient in conjunction with the bisphosphonate, it would be obvious to use these dosages because they are recommended. As stated above Daifotis discloses the kit and Kelly remedies the deficiencies by disclosing suitable blister packs. PAMF further remedies the combination by disclosing what doses are recommended for daily intake.

Although the combination of references does not explicitly teach the importance of not taking a bisphosphonate on the same day as calcium, Daifotis alone teaches that calcium that is a part of a blister pack comprising a bisphosphonate is not taken on the same day because one of the purposes of the calcium is so that the patient will take a single dosage each day. Therefore the patient would receive the benefits as disclosed by the Declaration and would avoid simultaneous daily dosing.

It is further asserted that the claims encompass embodiments that do not contain vitamin D; therefore none of the references need to teach or suggest the incorporation of vitamin D into the disclosed kits to meet the limitations of the instant claims.

It is noted Applicant has amended the claims to recite to be given subsequent to the bisphosphonate administration and on the days between the days when each unit dose bisphosphonate is taken". The limitation may be interpreted to mean that the nutrient may be taken on the same day but after taking the bisphosphonate as well as taking the nutrient on days bisphosphonate is not taken.

It is also further noted that there appears to be no mention of any negative effects of vitamin D when taken on the same day as a bisphosphonate. Therefore, for arguendo, even if it was found that the kits provide unexpected results, the results are not commensurate in scope with the instant claims because the nutrient may be vitamin D alone.

2) Claims 1, 2, 4, 11, 14, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Allendorf et al. (US 5,265,728) in further view of Palo Alto Medical Foundation (January 2002).

Applicant's Arguments

See Applicant's arguments above in regard to Daifotis. Applicant's arguments are the same as that for Kelly above. Allendorf does not teach administration of unit doses of an accompanying calcium-containing nutrient. It merely teaches that seven tablets in

the blister pack might be a placebo or non-active tablet the blister packs are generally to act as memory aids. Further, there is clearly no disclosure or suggestion of the amount of calcium, or vitamin D to be administered in the unit doses as presently claimed, e.g., about 400 mg to about 1500 mg of elemental calcium per day and about 100 IU to 10,000 IU per day.

See Applicant's arguments above for PAMF.

Examiner's Response

See Examiner's Response above in regard to Daifotis et al. In regard to Allendorf, Daifotis suggests methods of improving patient compliance by suggesting the compositions be stored in blister packs with memory aids. Allendorf et al. disclose such blister packs. Although Allendorf does not mention bisphosphonates, it mentions they are used to deliver tablets (Abstract). One of ordinary skill in the art would recognize the advantages of using the blister packs with the compositions of Daifotis because the blister packs are aids in helping the patients take their medication at the appropriate time. Although Allendorf does not teach calcium, it is used for its teaching of blister packs that use memory aids that assist in patient compliance. The blister packs comprise rows and columns and have the days of the week as a memory aid. Some blister packs have 4 rows which would include the 28 day period of the instant claim Figures). Therefore the blister packs will improve patient compliance and the alleged unexpected results asserted by Applicant do not appear to be unexpected. The amounts of calcium and vitamin D are disclosed by Palo Alto Medical foundation

(PAMF). PAMF discloses recommended daily doses and therefore remedies the deficiencies of Daifotis in view of Allendorf et al. See Examiner's Response above in regard to PAMF.

As stated above, Daifotis discloses the kit and Allendorf et al remedy the deficiencies by disclosing suitable blister packs. PAMF further remedies the combination by disclosing what doses are recommended for daily intake.

Although the combination of references does not explicitly teach the importance of not taking a bisphosphonate on the same day as calcium, Daifotis alone teaches that calcium that is a part of a blister pack comprising a bisphosphonate is not taken on the same day. Therefore the patient would receive the benefits as disclosed by the Declaration and would avoid simultaneous daily dosing.

Claims 1, 2, 4, 11, 14, 25 and 26 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612